

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P.,	)	
GALDERMA S.A. and NESTLÉ SKIN	)	
HEALTH S.A.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-1783 (RGA)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

**STIPULATION AND PROPOSED ORDER OF PARTIAL JUDGMENT OF NON-  
INFRINGEMENT AND DISMISSAL OF COUNTERCLAIMS**

**WHEREAS**, in this action, Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Nestlé Skin Health S.A. (collectively, “Galderma”) assert Claims 2, 14, and 15 of U.S. Patent No. 8,815,816 (the “’816 Patent”), as well as Claims 7 and 13 of U.S. Patent No. 8,362,069 (the “’069 Patent”). Each of the asserted dependent claims in the ’816 Patent depend from independent Claim 11; and the asserted dependent claims in the ’069 Patent depend (directly or indirectly) from independent claim 1;

**WHEREAS**, Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) has produced to Galderma its Abbreviated New Drug Application No. 210019, which describes Teva’s proposed 1% ivermectin cream (“Teva’s ANDA Product”);

**WHEREAS** Claims 2 and 11 of the ’816 Patent require, among other things, “a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol”;

**WHEREAS** Claim 1 of the '069 Patent requires, among other things, “at least one oily solvent to form an active phase, said active phase being devoid of any solvent for [ivermectin] distinct from said at least one oily solvent”;

**WHEREAS** the Court construed the term “a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol” as “a mixture of solvents and/or propenetrating agents in the emulsion that must be a mixture of at least two of propylene glycol, ethanol, isopropanol, butanol, Nmethyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol or mixtures thereof, but cannot include any other solvents and/or propenetrating agents” (D.I. 124 at 22-24);

**WHEREAS** the Court construed the term “oily solvent” as “organic solvent not miscible with water that can dissolve ivermectin excluding alcohols or glycols except octyl dodecanol” (D.I. 124 at 5-10);

**WHEREAS** all parties agree and stipulate that Teva’s ANDA Product as currently proposed does not infringe Claims 2, 14, and 15 of the '816 Patent under the Court’s construction of the “a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol” limitation;

**WHEREAS** all parties agree and stipulate that Teva’s ANDA Product as currently proposed does not infringe Claims 7 and 13 of the '069 Patent under the Court’s construction of the “oily solvent” limitation;

**WHEREAS** all parties agree and stipulate that Teva is therefore entitled to Partial Judgment of Non-Infringement of the '069 and '816 Patents and that Teva will dismiss Counts I, II, III, and IV of its Counterclaims concerning the '069 and '816 Patents without prejudice. The Parties further agree that such Partial Judgment is not a Final Judgment within the meaning of Fed. R. Civ. P. 54(b).

**NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED** that, Partial Judgment of Non-Infringement and Dismissal of Counterclaims I, II, III, and IV be entered as to U.S. Patent No. 8,815,816, and U.S. Patent No. 8,362,069, as set forth in the Proposed Order;

**IT IS FURTHER STIPULATED AND AGREED** that, barring reversal or modification of Partial Judgment of Non-Infringement, the parties shall take no further action in this lawsuit concerning any claim, counterclaim, or defense insofar as it relates to the '069 or '816 Patents. Galderma contends, that, but for the Court's claim constructions noted above, Teva would infringe the asserted claims; Galderma therefore reserves the right to appeal, at the appropriate time, this Partial Judgment of Non-Infringement for the purpose of obtaining appellate review of the Court's claim construction of the following limitations: (1) "oily solvent" and (2) "a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol," which are set forth in the Court's September 7, 2018 Memorandum Opinion (D.I. 124). Teva contends that, even under Galderma's proposed claim constructions, *see* D.I. 110 at pp. 9, 60, Teva would not infringe the asserted claims. Teva further contends that the asserted claims are invalid and therefore cannot be infringed. In addition, the parties agree that this stipulation is without prejudice to any claim construction, infringement, or non-infringement positions with respect to any other limitations of any other asserted claims in this matter; and

**IT IS FURTHER STIPULATED AND AGREED** that this Partial Judgment of Non-Infringement and Dismissal of Counterclaims is not a Final Judgment within the meaning of Fed. R. Civ. P. 54(b).

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and Nestlé Skin Health S.A.*

September 17, 2018

SO ORDERED on this \_\_\_\_ day of September, 2018.

\_\_\_\_\_  
UNITED STATES DISTRICT JUDGE